4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2021-N-1011]

Medical Devices; General and Plastic Surgery Devices; Classification of the Autofluorescence Detection Device for General Surgery and Dermatological Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the autofluorescence detection device for general surgery and dermatological use into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the autofluorescence detection device for general surgery and dermatological use's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on November 2, 2018.

FOR FURTHER INFORMATION CONTACT: Jessica Mavadia-Shukla, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4643, Silver Spring, MD 20993-0002, 301-348-1596, Jessica.Mavadia-Shukla@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the autofluorescence detection device for general surgery and dermatological use as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and

Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On September 27, 2017, FDA received AiBiomed, Corp.'s request for De Novo classification of the Parathyroid Detection (Model PTeye) System. Subsequently, on December 22, 2017, FDA received Fluoptics's similar request for De Novo classification of the Fluobeam 800 Clinic Imaging Device used with Fluocase 800 Control System. FDA reviewed both

requests in order to classify the devices under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the requests, we determined that the devices can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, on November 2, 2018, FDA issued orders to both requesters classifying the devices into class II. In this final order, FDA is codifying the classification of these devices by adding 21 CFR 878.4550.[1] We have named the generic type of device autofluorescence detection device for general surgery and dermatological use, and it is identified as an adjunct tool that uses autofluorescence to detect tissues or structures. This device is not intended to provide a diagnosis.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

[1] FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

Table 1--Autofluorescence Detection Device for General Surgery and Dermatological Use Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Electrical, mechanical, or thermal hazards leading to user injury or discomfort	Electromagnetic compatibility testing; Electrical, mechanical and thermal safety testing; Software verification, validation, and hazard analysis; and Labeling
Tissue, skin burn, or eye injury due to light and laser exposure	Light and laser exposure safety testing and Labeling
Infection and cross contamination	Sterilization validation, Shelf life testing, and Labeling
Adverse tissue reaction	Biocompatibility evaluation
False identification of target tissues or structures leading to errors in patient management (e.g., removal of healthy tissue or not removing diseased tissue)	In vivo performance testing; Software verification, validation, and hazard analysis; and Labeling

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in the guidance document "De Novo Classification Process (Evaluation of Automatic Class III Designation)" have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878--GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 878.4550 to subpart E to read as follows:

§ 878.4550 Autofluorescence detection device for general surgery and dermatological use.

(a) *Identification*. An autofluorescence detection device for general surgery and dermatological use is an adjunct tool that uses autofluorescence to detect tissues or structures. This device is not intended to provide a diagnosis.

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) In vivo testing under anticipated conditions of use must characterize the ability of the device to detect autofluorescent signals from tissues or structures consistent with the indications for use.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance testing must demonstrate the electromagnetic compatibility and electrical, mechanical, and thermal safety of the device.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Performance testing must demonstrate the sterility of patient-contacting components of the device.

(6) Performance testing must support the shelf life of device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.

(7) Performance testing must demonstrate laser and light safety for eye, tissue, and skin.

(8) Labeling must include the following:

(i) Instructions for use;

(ii) The detection performance characteristics of the device when used as intended; and

(iii) A shelf life for any sterile components.

Dated: April 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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